

TABLE OF CONTENTS

IN VITRO OCULAR TEST METHOD EXPERT PANEL ROSTER.....	iii
PREFACE	v
EXECUTIVE SUMMARY.....	vii
I. Isolated Rabbit Eye (IRE) Test Method.....	1
1.0 IRE Test Method Rationale.....	3
2.0 IRE Test Method Protocol Components	5
3.0 Substances Used for Previous Validation Studies of the IRE Test Method	10
4.0 <i>In Vivo</i> Reference Data Used for an Assessment of Test Method Accuracy.....	10
5.0 IRE Test Method Data and Results	13
6.0 IRE Test Method Accuracy.....	13
7.0 IRE Test Method Reliability (Repeatability/Reproducibility).....	16
8.0 Test Method Data Quality.....	17
9.0 Other Scientific Reports and Reviews.....	18
10.0 Animal Welfare Considerations (Refinement, Reduction, and Replacement)	18
11.0 Practical Considerations.....	19
12.0 Proposed Test Method Recommendations.....	20
13.0 IRE BRD References.....	24
14.0 Panel Report References	24
II. Isolated Chicken Eye (ICE) Test Method.....	27
1.0 ICE Test Method Rationale.....	29
2.0 ICE Test Method Protocol Components	32
3.0 Substances Used For Previous Validation Studies of the ICE Test Method	38
4.0 <i>In Vivo</i> Reference Data Used for an Assessment of Test Method Accuracy.....	38
5.0 ICE Test Method Data and Results	41
6.0 ICE Test Method Accuracy.....	42
7.0 ICE Test Method Reliability (Repeatability/Reproducibility).....	44
8.0 Test Method Data Quality.....	46
9.0 Other Scientific Reports and Reviews.....	47
10.0 Animal Welfare Considerations (Refinement, Reduction, and Replacement)	48
11.0 Practical Considerations.....	48
12.0 Proposed Test Method Recommendations.....	50
13.0 ICE BRD References.....	53
14.0 Panel Report References	53
III. Bovine Corneal Opacity and Permeability (BCOP) Test Method.....	55
1.0 BCOP Test Method Rationale.....	57
2.0 BCOP Test Method Protocol Components	59
3.0 Substances Used For Previous Validation Studies of the BCOP Test Method ...	63
4.0 <i>In Vivo</i> Reference Data Used for an Assessment of Test Method Accuracy.....	64
5.0 BCOP Test Method Data and Results	66
6.0 BCOP Test Method Accuracy.....	67
7.0 BCOP Test Method Reliability (Repeatability/Reproducibility)	69

8.0	Test Method Data Quality.....	70
9.0	Other Scientific Reports and Reviews.....	71
10.0	Animal Welfare Considerations (Refinement, Reduction, and Replacement)	71
11.0	Practical Considerations.....	71
12.0	Proposed Test Method Recommendations.....	72
13.0	BCOP BRD References.....	77
14.0	Panel Report References	77
IV.	Hen's Egg Test – Chorioallantoic Membrane (HET-CAM) Test Method.....	81
1.0	HET-CAM Test Method Rationale	83
2.0	HET-CAM Test Method Protocol Components.....	85
3.0	Substances Used For Previous Validation Studies of the HET-CAM Test Method	86
4.0	<i>In Vivo</i> Reference Data Used for an Assessment of Test Method Accuracy.....	86
5.0	HET-CAM Test Method Data and Results	90
6.0	HET-CAM Test Method Accuracy	91
7.0	HET-CAM Test Method Reliability (Repeatability/Reproducibility).....	93
8.0	Test Method Data Quality.....	95
9.0	Other Scientific Reports and Reviews.....	96
10.0	Animal Welfare Considerations (Refinement, Reduction, and Replacement)	96
11.0	Practical Considerations.....	97
12.0	Proposed Test Method Recommendations.....	98
13.0	HET-CAM BRD References.....	102
14.0	Panel Report References	102
V.	Proposed Reference Substances for Validation Studies.....	105
1.0	Adequacy and Completeness of the Proposed List of Reference Substances	107
2.0	Other Criteria that Should Be Addressed in the Selection of Reference Substances	109